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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,657	02/20/2001	Ulf Landegren	LANDEGREN=1A	5356

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,657

Applicant(s)

LANDEGREN ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Information Disclosure Statement (Paper No. 5) filed on May 10, 2001 has been entered.
2. The response to restriction requirement (Paper No. 10) filed on February 13, 2002, has been entered.
3. Applicant's election with traverse of claims in Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the Group I and II are related. This is not found persuasive because claims are grouped based on broadest claims as claim 1 and intended use of kit claims has no patentable weight. M.P.E.P. 2111.01 states that "any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966".

Applicants' argue that the probes in the Group II claims are not used in materially

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different processes, which is not found persuasive because the kits could be used in simple hybridization assays, or the probes could be used in cloning or applied to affinity columns as in purification assays. Further, additional search is required to review not only the patents in class 435, subclass 6 for Group I but also the patents in class 536, subclass 22.1 for Group II. Review of these additional searches is prima facie evidence of burden, which is not rebutted. The requirement is still deemed proper.

4. Claims 8-12 are dependent on non-elected species and therefore are not considered for examination. Claims 1-7, and 13-18 are considered for examination non-elected Group II claims 8-12 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a. Claims 1-7 and 13-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 is confusing for referring to the subject matter in the term "and/or". Thus it is unclear how the claims can simultaneously encompass all of these limitations (detection/ quantifying one or more analytes). The claim should refer to the subject matter in the alternative only, the replacement of the term "and/or" with "or" or the addition of dependent claims are suggested.

b. Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claims 13-18 are incomplete and indefinite for being incomplete sentences, which do not clearly indicate the subject matter.

c. Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-18 are incomplete and indefinite for being dependent on non-elected claims.

d. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is incomplete and indefinite for reciting '....combinations thereof'. It is not clear whether combinations thereof refers to the combinations between two different types of probes (such as nucleic acid-antibody combination) or between two similar type (such as peptide-peptide, nucleic acid-nucleic acid combinations).

e. Regarding claim 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1-7, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren (WO 97/00446).

Landgren teaches a method for detecting analyte(s) in a solution, wherein the method comprises binding of two or more proximity probes (oligonucleotides) to a respective binding site on the analyte, wherein the proximity probes are comprised of a binding moiety (interacting species modified with crosslinkable compounds such as lectins, receptors, antibodies, oligonucleotides) and allowing binding moiety to bind to the analyte (antibody-antigen) and the proximity probes interact with each other (oligonucleotides of neighbouring antibodies are conjugated to each other) and detecting the interaction between nucleic acids (oligonucleotides) (see page 3, paragraph 4, page 4, lines 1-8, 21-31). Landgren also teaches that the method comprises (i) amplification of the interacted nucleic acids and detection of amplified product (see page 4, lines 7-8,); binding moieties of the proximity probes selected from antibodies, lectin, receptors, nucleic acids (oligonucleotides) (see page 4, paragraph 5, and page 5, paragraph 5); detection of an unknown analyte in a solution, and screening ligand candidates (antibody-affinity reagents) (see page 6, paragraphs 1-3). Therefore the disclosure of Landegren meets the limitations in the instant claims.

b. Claims 1,3-5, and 7, 14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al. (4,988,617).

Landgren et al. teach a method for detecting analyte(s) (target nucleic acid) in a solution, wherein the method comprises binding of two or more proximity probes (oligonucleotides) to a respective binding site on the analyte, wherein the proximity probes are comprised of a binding moiety (biotin) and allowing binding moiety to bind to the analyte and the proximity probes interact with each other (adjacent oligonucleotide probes join each other) and detecting the interaction between nucleic acids (oligonucleotides) (see column 3, lines 1-38, column 4, lines

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34-50, column 10, 48-60). Landgren et al. also teach that the method (i) comprises binding moieties of the proximity probes selected from antibodies, carbohydrate and complementary strands of DNA (see column 10, lines 60-67); (ii) can be used to detect infectious agents in a test substance (see column 4, lines 12-19). Therefore the disclosure of Landegren et al. meets the limitations in the instant claims.

Claims 1,3-5, 7, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al. (5,871,921).

Landgren et al. teach a method for detecting analyte(s) (target nucleic acid) in a solution, wherein the method comprises binding of two or more proximity probes (oligonucleotides) to a respective binding site on the analyte, wherein the proximity probes are comprised of a binding moiety (intermediate segments) and allowing binding moiety to bind to the analyte and the proximity probes interact with each other (adjacent oligonucleotide probes join each other interlocking target nucleic acid) and detecting the interaction between nucleic acids (oligonucleotides) (see columns 13-14, claims 1, 2,6-9, column 3, lines 25-57, 62-67). Landgren et al. also teaches that the method comprises binding moieties of the proximity probes selected from protein, polypeptide, carbohydrate and synthetic polymer (see column 14, lines 9-12 or claim 9); method can be used to screen DNA or RNA libraries (see column 4, lines 2-5). Therefore the disclosure of Landegren et al. meets the limitations in the instant claims. No claims are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{SPC}
Suryaprabha Chunduru
March 19, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER